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REVISED 10/15/86

Microfiche No.	OTSG0540695	
New Doc I.D.	Old Doc I.D.	
86-920001005		
Date Produced	Date Received	TSCA section
7/23/92	7/30/92	8D
Submitting Organization	AMER CYANAMID INC	
Contractor	BUSHY RUN RES CTR	
Document Title	EVALUATION OF THE POTENTIAL OF TOLUENE DIISOCYANATE TO PRODUCE PULMONARY HYPERSENSITIVITY IN GUINEA PIGS WITH COVER LETTER DATED 072792	
Chemical Category	TOLUENE DIISOCYANATE	



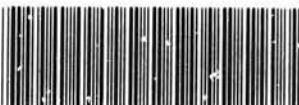
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92 JUL 30 PM 1:15

American Cyanamid Company
Chemicals Group
Toxicology and Product Stewardship Department
One Cyanamid Plaza
Wayne, NJ 07470
Fax: 201-831-2621

July 27, 1992



86920001005

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
Room L-100
401 M Street, S.W.
Washington, DC 20460

Attention: 8(d) Health & Safety Reporting Rule
(Notification/Reporting)

Dear Sir/Madam:

RE: TOLUENE DIISOCYANATE [CAS 26471-62-5]

I am enclosing a copy of a report entitled "Evaluation of the Potential of Toluene Diisocyanate (CT-290-87) to Produce Pulmonary Hypersensitivity," which was received July 27, 1992. This study was notified in a letter from Joan L. Gallagher dated February 22, 1988.

If you have any questions please contact me at (201) 831-2534.

Sincerely,

Patricia Ann Vernon
Patricia Ann Vernon
Associate Toxicologist



BUSHY RUN RESEARCH CENTER

6702 Mellon Road, Export, Pennsylvania 15632-8902

Telephone (412) 733-5200
Telecopier (412) 733-4804

CONTAINS NO CBP

STUDY TITLE

Evaluation of the Potential of Toluene Diisocyanate (CT-290-87)
to Produce Pulmonary Hypersensitivity

TEST SUBSTANCE

Toluene Diisocyanate (CT-290-87)

RECEIVED

AUTHOR

H. D. Burleigh-Flayer

JUL 27 1992

P. A. VERNON

STUDY COMPLETION DATE

July 23, 1992

PERFORMING LABORATORY

Bushy Run Research Center (BRRC)
Union Carbide Chemicals and
Plastics Company Inc.
6702 Mellon Road
Export, PA 15632-8902

LABORATORY PROJECT ID

91N0106

SPONSOR

American Cyanamid Company
Chemicals Group
One Cyanamid Plaza
Wayne, NJ 07470

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EQ

**Evaluation of the Potential of Toluene Diisocyanate (CT-290-87)
to Produce Pulmonary Hypersensitivity**

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

The portions of the in-life phase of this study conducted at BRRC meet the requirements of Toxic Substances Control Act (TSCA) Good Laboratory Practice Standards, 40 CFR Part 792. The reporting of study results does not meet the requirements of the above guideline as per the request of the Sponsor. The data generated for the study and this summary were not reviewed by the BRRC Quality Assurance Unit. All data and this summary will be retained by BRRC.

Study Director:

Heather D. Burleigh-Flayer, Ph.D. 7-23-92
Heather D. Burleigh-Flayer, Ph.D. Date

**Evaluation of the Potential of Toluene Diisocyanate (CT-290-87)
to Produce Pulmonary Hypersensitivity**

SUMMARY

This study followed the protocol (BRRC 87-57-04-PH-A) and protocol amendments (standard and No. 2); Protocol Amendment No. 2 states that the data on toluene diisocyanate will be reported as a brief summary. The following work was performed in conjunction with a previously reported study (BRRC Project Report 50-606). The materials and methods used for this portion of the study were similar to that reported in BRRC Project Report 50-606.

The potential of toluene-diisocyanate (TDI; CT-290-87; CAS No. 584-84-9) to produce respiratory hypersensitivity in the guinea pig was investigated. Female Hartley guinea pigs were exposed to 0.6 ppm of TDI vapor for 3 hours/day for 5 days in an attempt to sensitize them. Control animals were exposed to filtered air only. No exposure-related clinical signs were observed in the TDI-exposed animals. Gross pathologic findings at scheduled sacrifice indicated that only 2 of the 12 guinea pigs exposed to TDI had evidence of color changes in the lungs. Two weeks following the induction period, the respiratory rates of guinea pigs were monitored during challenge with an aerosol of guinea pig serum albumin (GPSA) followed by an aerosol of TDI-GPSA conjugate. A slight pulmonary response was observed for two animals (87-14720 and 87-14724) during their first challenge. However, their response did not meet the criteria of a pulmonary hypersensitivity response (a 36% sustained increase in respiratory rate over their mean preexposure rate). Both of these guinea pigs showed a > 20% increase in respiratory rate which was sustained for several minutes during the challenge. Neither of these guinea pigs had evidence of pulmonary lesions at necropsy. Positive antibody titers were observed in the sera of TDI-exposed animals. Antibody titers ranged from 1:1600 to 1:35000. After exposures, guinea pigs were each challenged with intradermal injections of GPSA, TDI-GPSA conjugate, TDI, saline, and acetone. Since the TDI-GPSA treatment did not produce reactions that were substantially different from control doses (either on inhalation controls or solvent controls) and topical challenge doses of TDI produced no reactions, it is concluded that the test animals were not dermally sensitized to TDI following inhalation exposures.

Evaluation of the Potential of Toluene Diisocyanate (CT-290-87)
to Produce Pulmonary Hypersensitivity

Study Data

(42 Pages)

COMPOUND: T01 PROJECT #: 87-S1-8006 BIRC #: 50-567
 TARGET: O.6 rpm SPECIES: C. P. SEX: Femal
 EXPOSURE LEVEL: ACTUAL:

INDIVIDUAL ANIMAL OBSERVATIONS

REVIEWED BY: John D. Scott REVIEWED BY: UN
DATE 11/14/02 DATE 11/14/02

COMPOUND: TOT PROJECT #: 80008 B.R.C. #: _____
EXPOSURE LEVEL: ACTUAL: TARGET: Cleptor SPECIES: G. P.
SEX: Male

INDIVIDUAL ANIMAL OBSERVATIONS

REVIEWED BY: Dr. G. L. RIA REVIEWED BY: N/A
ED BY: WRC DATE: 7/7/10

COMPOUND: TOT

EXPOSURE LEVEL: TARGET: 0.6 ppm
ACTUAL: _____

PROJECT #: 2009

BRC #: 50-56 A

EXPOSURE LEVEL: **TARGET:** 0.6 ppm
ACTUAL: _____

SPECIES: F. P.

SEX: Female

INDIVIDUAL ANIMAL OBSERVATIONS

OBSERVED BY: John D. Jones

584
11/1944

REVIEWED BY: _____ NF

BAIE

BRRC Report 9IN0106
Appendix 1
Page 4

PROJECT NO. 1PGPPS1
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR NO. 187-67-80006

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TDI/TMXDI
GROSS AND MICROSCOPIC OBSERVATIONS

10:30 02-SEP-87 PAGE 13

ANIMAL NO. 14703 GROUP: 0.6 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEM = 1
PROSECTOR: MHS WEIGHER: MHS TRIMMER: PATHOLOGIST: EMF GRADE

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GROSS: TOTAL BODY	MESENTERY/OM'TUM	PERITONEUM	PERITONEAL CAV
LUNGS	2.000	0.000		PLEURA	THORACIC CAV	HEART	PERICARDIAL CAV
TERMINAL BODY WT	0.0			AORTA	SALIVARY GL	ORAL/PHARYNGEAL	ESOPHAGUS
				LIVER	PANCREAS	DUODENUM	JEJUNUM
				ILEUM	CECUM	COLON	ANUS
				PARATHYROID GL	ADRENAL GL	SKIN, TREATED	SKIN, UNTREATED
				SUBCUTIS	HEAD	SPLEEN	LYMPH ND, S-BAR
				LYMPH ND, MES	THYMIC REGION	BONE/JOINT	BONE, STERNUM
				BONE, FEMUR	BONE, VERTEBRA	DIAPHRAGM	EYE
				OVARIES	OVIDUCT	CERVIX	VULVA
				LARYNX	TRACHEA	LUNGS	KIDNEYS

GRADE CODE: 1-MINIMAL, 2-WILD, 3-MODERATE, 4-MARKED,
5-SEVERE, P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO.: PGPPS1
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR NO.: 87-87-80008

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TDI/IMXDI
GROSS AND MICROSCOPIC OBSERVATIONS

10:30 02-SEP-87 PAGE 14

ANIMAL NO. 14702 GROUP: 0.6 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEM = 1
PROSECTOR: MAM WEIGHER: HHS TRIMMER: PATHOLOGIST: EMF GRADE

ORGAN WEIGHT	ABS.(g)	REL.	LUNGS	GROSS: COLOR CHANGE, FOCAL/MULTIFOCAL DARK RED, ALL LOBES	
LUNGS	3.732	0.000			
TERMINAL BODY WT	0.0				

NO SIGNIFICANT CHANGES OBSERVED

GROSS: TOTAL BODY	MESENTERY/OM' TUM PERITONEUM	PERITONEAL CAV
PLEURA	THORACIC CAV	PERICARDIAL CAV
AORTA	SALIVARY GL	ESOPHAGUS
LIVER	PANCREAS	DUODENUM
ILEUM	CECUM	COLON
PARATHYROID GL	ADRENAL GL	SKIN, TREATED
SURCUTIS	HEAD	SPL'EN
LYMPH ND, MES	THYMIC REGION	BONE/JOINT
BONE, FEMUR	BONE, VERTEBRA	DIAPHRAGM
OVARIES	OVIDUCT	CERVIX
LARYNX	TRACHEA	KIDNEYS

GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-MARKED,
5-SEVERE, P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO.: PGPPS1
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR NO.: 87-57-00006

PULMONARY HYPERSensitivity ASSESSMENT OF TDI/TMXDI GROSS AND MICROSCOPIC OBSERVATIONS

10:38 02-SEP-87 PAGE 15

ANIMAL NO. 14007 GROUP: 0.6 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEM = 1
 PROSECTOR: MAM WEIGHER: MHS TRIMMER: PATHOLOGIST: EMP GRADE
 ORGAN WEIGHT ABS.(G) REL. LIVER GROSS: COLOR CHANGE, FOCAL/MULTIFOCAL
 LUNGS 3.006 0.000 7X3MM, DARK RED FOCUS, RIGHT MEDIAN LOBE;
 TERMINAL BODY WT 0.0 APPEARS TO BE CONTAINED WITHIN THE CAPSULE
 SKIN, TREATED GROSS: EXCORIATION SEVERAL AREAS, 1MM TO 2MM
 NO SIGNIFICANT CHANGES OBSERVED GROSS: TOTAL BODY MESENTERY/DORSUM PERITONEUM PERITONEAL CAV.
 PLEURA THORACIC CAV. HEART PERICARDIAL CAV.
 AORTA SALIVARY GL. ORAL/PHARYNGEAL ESOPHAGUS
 PANCREAS DUODENUM JEJUNUM ILEUM
 CECUM COLON ANUS PARATHYROID GL.
 ADRENAL GL. SKIN, UNTREATED SUBCUTIS HEAD
 SPLEEN LYMPH ND, S-MAN LYMPH ND, BES THYMUS REGION
 BONE/JOINT BONE, STERNUM BONE, FEMUR BONE, VERTEBRA
 DIAPHRAGM EYE OVARIES OVIDUCT
 CERVIX VULVA LARYNX TRACHEA
 LUNGS KIDNEYS

GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-MARKED,
5-SEVERE, P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO. ICPGPPS1
 SPONSOR/AMERICAN CYANAMID CO.
 SPONSOR NO. 107-07-00305

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TOI/TMKD1
 GROSS AND MICROSCOPIC OBSERVATIONS

ORGAN	WEIGHT	ABS. (g)	REL.	NO. SIGNIFICANT CHANGES OBSERVED	GROSS: TOTAL BODY	PLEURA	AORTA	LIVER	CECUM	DUODENUM	PANCREAS	STOMACH	JEJUNUM	ANUS	PERITONEAL CAV	PERICARDIAL CAV	ESOPHAGUS	RECTUM	HEART	THORACIC CAV	SALIVARY GL	LARYNGEAL	MESENTERY/OM'THR PERITON TUN		
TOTAL BODY WT	7.0	6.000	8.000																						
Lungs	3.443																								
PARATHYROID GL.																									
SUBCUTIS																									
LYMPH ND. MES																									
BONE, FEMUR																									
OVARIES																									
LARYNX																									
TRACHEA																									
DIDNEY'S																									

GRADE CODE: 1-MINIMAL, 2-BILLO, 3-MODERATE, 4-MARKE,
 5-SEVERE, P-PRESENT
 ()-FOCAL, (())-MULTIFOCAL, NO PARENTHESIS-DIFFUSE

PROJECT NO.:FOPPS1
SPONSOR:AMERICAN CYANAMID CO.
SPONSOR NO.187-87-80000

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TDI/TMXDI
GROSS AND MICROSCOPIC OBSERVATIONS

10:30 02-SEP-87 PAGE 17

ANIMAL NO.	14003	GROUP:	0.0 PPM	FEMALE	SCHEDULED KILL	7/15/87	STUDY DAY	28 HOURS POST MORTEM = 1	GRADE
PROSECUTOR:	HHS	WEIGHER:	HHS	TRIMMER:		PATHOLOGIST:	EHF		
ORGAN WEIGHT	ABS.(g)	REL.		SKIN, TREATED	GROSS: EXCORIATION MULTIFOCAL, MILD				
LUNGS	3.815	8.000		LUNGS	GROSS: COLOR CHANGE, FOCAL/MULTIFOCAL ALL LOBES MOTTLED LIGHT AND DARK PINK				
TERMINAL BODY WT	0.0								
NO SIGNIFICANT CHANGES OBSERVED									
GROSS: TOTAL BODY									
PLEURA	WESENTARY/OM'TUM	PERITONEUM	PERITONEAL CAV						
AORTA	THORACIC CAV	HEART	PERICARDIAL CAV						
LIVER	SALIVARY GL	ORAL/PHARYNGEAL	ESOPHAGUS						
ILEUM	PANCREAS	DUODENUM	JEJUNUM						
PARATHYROID GL	CECUM	COLON	ANUS						
HEAD	ADRENAL GL	SKIN, UNTREATED	SUBCUTIS						
THYMIC REGION	SPLEEN	LYMPH ND, S-MAN	LYMPH ND, MES						
BONE, VERTEBRA	BONE/JOINT	BONE, STERNUM	BONE, FEMUR						
OVIDUCT	DIAPHRAGM	EYE	OVARIES						
TRACHEA	CERVIX	VULVA	LARYNX						

GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-MARKED,
5-SEVERE, P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO.: PGPPS1
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR NO.: 187-87-80000

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TDI/TMXDI
GROSS AND MICROSCOPIC OBSERVATIONS

16:30 02-SEP-87 PAGE 18

ANIMAL NO. 14717 GROUP: 0.6 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEM = 1
PROSECUTOR: MAN WEIGHER: MRS TRIMMER: PATHOLOGIST: EMF GRADE

ORGAN WEIGHT	ABS.(g)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GROSS: TOTAL BODY	MESENTERY/OM'TUM PERITONEUM	PERITONEAL CAV
LUNGS	3.401	0.000		PLEURA	HEART	PERICARDIAL CAV
TERMINAL BODY WT	0.0			AORTA	SALIVARY GL.	ESOPHAGUS
				LIVER	PANCREAS	JEJUNUM
				ILEUM	CECUM	ANUS
				PARATHYROID GL	ADRENAL GL	SKIN, TREATED
				SUBCUTIS	HEAD	SPLEEN
				LYMPH ND, MES	THYMIC REGION	BONE/JOINT
				BONE, FEMUR	BONE, VERTEBRA	DIAPHRAGM
				OVARIES	OVIDUCT	CERVIX
				LARYNX	TRACHEA	LUNGS
						KIDNEYS

GRADE CODE: 1-MINIMAL, 2-WILD, 3-MODERATE, 4-MARKED,
5-SEVERE. P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO. ICPPS1
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR NO. 187-B7-80000

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TDI/TMXDI
GROSS AND MICROSCOPIC OBSERVATIONS

16:38 02-SEP-87 PAGE 19

ANIMAL NO. 14000 GROUP: 0.6 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEM = 1 GRADE
PHOSECTOR: MMS WEIGHER: MMS TRIMMER: PATHOLOGIST: EHF

ORGAN WEIGHT	ABS.(g)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GROSS: TOTAL BODY	MESENTERY/OM'TUM PERITONEUM	PERITONEAL CAV
LUNGS	3.333	0.000		PLEURA	HEART	PERICARDIAL CAV
TERMINAL BODY WT	0.6			AORTA	SALIVARY GL	ESOPHAGUS
				LIVER	PANCREAS	DUODENUM
				ILEUM	CECUM	JEJUNUM
				PARATHYROID GL	ADRENAL GL	COLOR
				SURCUTIS	HEAD	SKIN, TREATED
				LYMPH NT, MES	THYMIC REGION	SKIN, UNTREATED
				BONE, FEMUR	BONE, VERTEBRA	LYMPH ND, S-MAN
				OVARIES	OVIDUCT	BONE, STERNUM
				LARYNX	TRACHEA	EYE
						VULVA
						KIDNEYS

GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-MARKED,
5-SEVERE. P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO.: POPPSI
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR ID: 107-87-80000

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TD1/TMXD1
GROSS AND MICROSCOPIC OBSERVATIONS

16:38 02-SEP-87 PAGE 20

ANIMAL NO. 14786 GROUP: 0.0 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEM = 1
PROSECTOR: MAN WEIGHER: MHS TRIMMER: PATHOLOGIST: EHF GRADE

ORGAN WEIGHT	ABS.(g)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GROSS: TOTAL BODY	MESENTERY/DR'RY TUN PERITONEUM	PERITONEAL CAV	
LUNGS	3.055	0.000		PLEURA	THORACIC CAV	HEART	PERICARDIAL CAV
TOTAL BODY WT	0.0			AORTA	SALIVARY GL	ORAL/PHARYNGEAL	ESOPHAGUS
				LIVER	PANCREAS	DUODENUM	JEJUNUM
				ILFUM	CECUM	COLOR	ANUS
				PARATHYROID GL	ADRENAL GL	SKIN, TREATED	SKIN, UNTREATED
				SURCUTIS	MED	SPLEEN	LYMPH ND, S-MAN
				LYMPH ND, MES	THYMIC REGION	BONE/JOINT	BONE, STERNUM
				BONE, FEMUR	BONE, VERTEBRA	DIAPHRAGM	EYE
				OVARIES	OVIDUCT	CERVIX	VULVA
				LARYNX	TRACHEA	LUNGS	KIDNEYS

GRADE CODE: 1-MINIMAL, 2-WILD, 3-MODERATE, 4-MARRED,
5-SEVERE, P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO. I.POPPS1
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR NO. 107-87-80008

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TDI/TMAD1
GROSS AND MICROSCOPIC OBSERVATIONS

16:38 02-SEP-87 PAGE 21

ANIMAL NO. 14006 GROUP: 0.0 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEN = 1
PROSECUTOR: DAW WEIGHER: HHS TRIMMER: PATHOLOGIST: EMF GRADE

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GROSS: TOTAL BODY	MESENTERY/OM'TUM	PERITONEUM	PERITONEAL CAV
LUNGS	4.438	0.000		PLEURA	THORACIC CAV	HEAR.	PERICARDIAL CAV
TERMINAL BODY WT	0.0			AORTA	SALIVARY GL	ORAL/PHARYNGEAL	ESOPHAGUS
				LIVER	PANCREAS	DUODENUM	JEJUNUM
				ILEUM	CECUM	COLON	ANUS
				PARATHYROID GL	ADRENAL GL	SKIN, TREATED	SKIN, UNTREATED
				SUBCUTIS	HEAD	SPLEEN	LYMPH ND, S-MAN
				LYMPH ND, MES	THYMIC REGION	BONE/JOINT	BONE, STERNUM
				BONE, FEMUR	BONE, VERTEBRA	DIAPHRAGM	EYE
				OVARIES	OVIDUCT	CERVIX	VULVA
				LARYNX	TRACHEA	LUNGS	KIDNEYS

GRADE CODE: 1-MINIMAL, 2-WILD, 3-MODERATE, 4-MARKED,
5-SEVERE, P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO.: PGPPS1
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR NO.: 87-87-80008

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TDI/TMXD1
GROSS AND MICROSCOPIC OBSERVATIONS

10:38 02-SEP-87 PAGE 22

ANIMAL NO. 14726 GROUP: 1.0 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEM = 1
PROSECTOR: MAM WEIGHER: MHS TRIMMER: PATHOLOGIST: EMF

GRADE

ORGAN WEIGHT	ABS. (g)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GROSS; TOTAL BODY	MESENTERY/OM'TUM PERITONEUM	PERITONEAL CAV
LUNGS	3.207	0.000		PLEURA	THORACIC CAV	PERICARDIAL CAV
TOTAL BODY WT	0.0			AORTA	SALIVARY GL	ESOPHAGUS
				LIVER	PANCREAS	DUODENUM
				ILEUM	CECUM	COLON
				PARATHYROID GL	ADRENAL GL	SKIN, TREATED
				SUBCUTIS	HEAD	SPLEEN
				LYMPH ND, MES	THYMIC REGION	BONE/JOINT
				BONE, FEMUR	BONE, VERTEBRA	DIAPHRAGM
				OVARIES	OVIDUCT	CERVIX
				LARYNX	TRACHEA	LUNGS
						KIDNEYS

GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-MARKED.
5-SEVERE, P-PRESENT
()-FOCAL, ()-MULTIFOCAL, NO PARENTHESES-DIFFUSE

16138 02-SEP-87 PAGE 23

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TD1/TBBD1

PROJECT NO. I-PAPPS1

SPONSOR: AMERICAN CYANAMID CO.

SPONSOR ID: 107-97-U0008

SPECIMEN ID: 107-97-U0008

ANIMAL NO. 14707 GROUP 0.0 ppm

PROSECUTOR: HHS

WEIGHT: 100G

SEX: FEMALE

STRAIN: CBA

TESTER: HHS

ORGAN WEIGHT	REL.	NO SIGNIFICANT CHANGES OBSERVED	GROSS TOTAL BODY	PERITONEAL CAV		
				MESENTERIC/GM-TUN	PERITONEUM	HEART
LUNGS	ABS. (1)	0.000	PLEURA	THORACIC CAV		
TERMINAL BODY WT	3.120	0.0	AORTA	DUODENAL		
			LIVER	DUODENUM		
			PANCREAS	COLUMN		
			ILEUM	COLON		
			PARATHYROID GL.	TREATED		
			SUBCUTIS	SKIN, UNTREATED		
			LYMPH ND, MTS	ADRENAL GL.		
			BONE, FIBUR	HEAD		
			OVARIES	THYMIC REGION		
			LARYNX	BONE, VERTEBRA		
				OVIDUCT		
				DIAPHRAGM		
				CERVIX		
				TRACHEA		
				LUMOS		

GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-BARRED.

5-SEVERE, P-PRESENT

()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE

PROJECT NO.: PGPPS1
SPONSOR: AMERICAN CYANAMID CO.
SPONSOR NO.: 187-87-00000

PULMONARY HYPERSENSITIVITY ASSESSMENT OF TDI/TMXD1
GROSS AND MICROSCOPIC OBSERVATIONS

10:30 02-SEP-87 PAGE 24

ANIMAL NO. 14723 GROUP: 0.6 PPM FEMALE SCHEDULED KILL 7/15/87 STUDY DAY 28 HOURS POST MORTEM = 1
PROSECUTOR: MAM WEIGHER: MRS TRIMMER: PATHOLOGIST: EHF

GRADE

ORGAN WEIGHT	ABS.(g)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GROSS: TOTAL BODY	MESENTERIC/OM'TUM PERITONEUM	PERITONEAL CAV
LUNGS	3.302	0.000		PLEURA	THORACIC CAV	HEART
TERMINAL BODY WT	0.0			AORTA	SALIVARY GL	ORAL/PHARYNGEAL
				LIVER	PANCREAS	ESOPHAGUS
				ILEUM	CECUM	DUODENUM
				PARATHYROID GL	ADRENAL GL	COLON
				SUBCUTIS	SKIN, TREATED	JEJUNUM
				HEAD	SPLEEN	ANUS
				LYMPH ND, MES	THYMIC REGION	LVMPH ND, S-MAN
				BONE, FEMUR	BONE, VERTEBRA	BONE, STERNUM
				OVARIES	OVIDUCT	EYE
				LARYNX	TRACHEA	VULVA
						KIDNEYS

GRADE CODE: 1-MINIMAL, 2-WILD, 3-MODERATE, 4-MARKED,
5-SEVERE, P-PRESENT
()-FOCAL, (())-MULTIFOCAL, NO PARENTHESES-DIFFUSE



Assay Run #: 1

Report of Results
for Assay 9400
TBI Antibody Screen

Report Printed: 11/04/97
Page #: 1

Project #: 0-99100
S.O. Case #: 132-03572-3

Approval:

A handwritten signature is placed over the "Approval:" line.

Sample Description
S1000 PIG SPERM PR00 700-425 EISW R.M.

Marker	Serum	Result	Titer	Comments
S100044-01	14-03 07-10-97 DAY 21+	ERDF 2 - TBI EXPOSED	-	1:10000
S100045-01	14-03 07-10-97 DAY 21+	ERDF 2 - TBI EXPOSED	-	1:3500
S100044-01	14-03 07-10-97 DAY 21+	ERDF 2 - TBI EXPOSED	-	1:2000
S100046-01	14-03 07-10-97 DAY 21+	ERDF 2 - TBI EXPOSED	-	1:6000
S100046-01	14-03 07-10-97 DAY 21+	ERDF 2 - TBI EXPOSED	-	1:10000
S100047-01	14-03 07-10-97 DAY 21+	ERDF 2 - TBI EXPOSED	-	1:2000

ELISA Information
Negative Serum Dilution: 0.040 +/- 0.030
Titers: Dilution of Serum at > 50
Mean % of Negative
Titers Positive Control: 1:21167 +/- 3139

Dr. Richard Davis
Dr. Heather Burleigh-Floyer
R.D 4
Mellon Road
Expoit, PA 15632

Report Details



Assay Run #: 1

Report of Results
for Assay 9930
TDI Antibody Screen

Report Printed: 11/06/97
Page #: 2

Project #: 0-99130
P.O./CON #: 132-21972-3

Approve!

A handwritten signature in black ink, appearing to read "M.H. Davis".

Sample Description: GUINEA PIG SERUM Project 700-425 EIGHT RUN

Incubation Sample #	Sample Date	Incubation Continued	Result: TITER	Comments
71004948	01	14-704 07-10-97(DAY 21)	GROUP 2 - TDI EXPOSED	- 1:6400
71004949	01	14-702 07-10-97 (DAY 21)	GROUP 2 - TDI EXPOSED	- 1:6400
71004950	01	14-717 07-10-97(DAY 21)	GROUP 2 - TDI EXPOSED	- 1:1600
71004951	01	14-710 07-10-97(DAY 21)	GROUP 2 - TDI EXPOSED	- 1:6400
71004952	01	14-703 07-10-97(DAY 21)	GROUP 2 - TDI EXPOSED	- 1:6400
71004953	01	14-724 07-10-97(DAY 21)	GROUP 2 - TDI EXPOSED	- 1:6400
71004954	01	14-695 07-10-97(DAY 21)	GROUP 2 - TDI EXPOSED	- 1:16000
71004955	01	14-723 07-10-97(DAY 21)	GROUP 2 - TDI EXPOSED	- 1:16000
71004956	01	14-697 07-10-97(DAY 21)	GROUP 2 - TDI EXPOSED	- 1:16000

TEST INFORMATION

Negative Serum OD= 0.049 +/- 0.030

Titer: Dilution of Serum at +/- 50

mean OD of Negative

Titer Positive Control= 1:21167 +/- 3109

Dr. Richard Davis
Dr. Heather Burleigh-Flyer
R.D. 4
Mellon Road
Exeter, PA 15632

Mental Health



Assay Run #: 1

Report of Results
for Assay 5520
TCI Antibody Screen

Report Printed: 11/06/87
Page #: 3

Project #: 0609130
F.O. ID#: 132-23972-3

Approval:

A handwritten signature in black ink, appearing to read "W.A. Jurs".

Sample Description

GUINEA PIG SERUM PRJ# 700-405 BSL#V RIN

Incubator	Sample	Result.	Comments	
Sample #	Date	Titer		
71004532	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:4000
71004539	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:5000
71004559	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:11000
71004561	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:6000
71004561	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:14000
71004562	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:1500
71004563	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:5000
71004564	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:4000
71004565	01	14-09 07-15-87(DAY 26)	OPDF 2 - TCI EXPOSED	- 1:4000

TEST INFORMATION

Negative Serum OD= 0.049 +/- 0.010

Titer: Dilution of Serum at 1:50

mean OD of Negative

Titer Positive Control= 1:21167 +/- 3189

Dr. Richard Davis
Dr. Heather Burleigh-Flyer
R.D 4
Mellon Road
Export, PA 15632

Normal Levels

Guinea Pig Skin Sensitization Testing Dosing

Group: CONTROL Date: 7-11-87
Material/Sample No: 1. TPI - GPCA / 50-3M 4. TPI / 50-56A
Vehicle/Sample No: 1. SAGINE 2. ACERTUVA

HDB-F/11f/1194Z
07/02/87

H.B. Flanger 3/29/68

Guinea Pig # 87-14694 | CONTROL-TOI | Guinea Pig # 87-14696

	<u>5</u> 0.01% TOI	<u>6</u> 0.1% TOI	<u>7</u> 100% ACETONE		<u>5</u> 0.01% TOI	<u>6</u> 0.1% TOI	<u>7</u> 100% ACETONE
Head	0.333% 6PSA	0.01% TOI-6PSA	0.1% TOI-6PSA	Tail	0.333% 6PSA	0.01% TOI-6PSA	0.1% TOI-6PSA
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>		<u>1</u>	<u>2</u>

Guinea Pig # 87-14701

Guinea Pig # 87-14704

	<u>5</u> 0.01% TOI	<u>6</u> 0.1% TOI	<u>7</u> 100% ACETONE		<u>5</u> 0.01% TOI	<u>6</u> 0.1% TOI	<u>7</u> 100% ACETONE
Head	0.333% 6PSA	0.01% TOI-6PSA	0.1% TOI-6PSA	Tail	0.333% 6PSA	0.01% TOI-6PSA	0.1% TOI-6PSA
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>		<u>1</u>	<u>2</u>

Guinea Pig #

Guinea Pig #

	<u>5</u>	<u>6</u>	<u>7</u>		<u>5</u>	<u>6</u>	<u>7</u>	
Head	1	2	3	Tail	1	2	3	Tail

24.2.88

CONTROL

TPI Guinea Pig Skin Sensitization - Challenge Readings
Material: TPI-6PSA Sample No.: 60-232 Conditions: AA

	Date:	7-11	7-12-87	7-13-87				
Guinea Pig No.:	87-N694							
Sex:	M							
Site/Time:		1	2	3	4	5	6	7
Dosed by:		✓	✓	✓	✓	✓	✓	✓

Erythema & Eschar Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-11-87	1	1	1	0	0	0	0
1 day	7-12-87	0	0	0	0	0	0	0
2 days	7-13-87	0	1	1	0	0	0	0

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-11-87	0	0	0	0	0	0	0
1 day	7-12-87	0	0	0	0	0	0	0
2 days	7-13-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

Initials Dr. J.W. Dickey Date 7-11-87
H.B. F. Hayes 3/29/87

KEY TO ABBREVIATIONS:

Severe Score
D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score
d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

WPC/11f/11752-2
06-30-87

Conquer

Guinea Pig Skin Sensitization - Challenge Readings

Material: TPE-~~GPA~~

Sample No.: SP-374. Conditions:

10A

Date:	7-11-57	7-12-57	7-13-57			
Guinea Pig No.:	51-1496					→
Sex:	♀					↗
Site/Time:	1	2	3	4	5	6
Dosed by:	✓	✓	✓	✓	✓	✓

Erythema & Eschar Formation

Edema Formation

Other Irritation or Effects

Specific Effects/Remarks:

Initials D. M. Dixit Date 7-1-87
H B F Leinen - 3/24/88

KEY TO ABBREVIATIONS:

SERVIA SCOTS

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Scores

d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

**WPC/11f/1175Z-2
06-30-87**

CONTINUE

TOI Guinea Pig Skin Sensitization - Challenge Readiness

Material: TOI-6RA Sample No.: 50-3A Conditions: PK

Date:	7-17-87	7-18-87	7-19-87				
Guinea Pig No.:	50-3A						
Sex:	M						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	✓	✓	✓	✓	✓	✓	✓

Erythema & Eschar Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-17-87	0	0	0	0	0	0	0
1 day	7-18-87	0	1	0	0	0	0	0
2 days	7-19-87	0	0	0	0	0	0	0

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-17-87	0	0	0	0	0	0	0
1 day	7-18-87	0	2	0	0	0	0	0
2 days	7-19-87	0	2	0	0	0	0	0

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

Initials JW Rb Date 7-17-87
FB F Year 3/21/88

KEY TO ABBREVIATIONS:

Severe Score
D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score
d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

WPC/11f/11752-2
06-30-87

CONTROL - TPI

TPI Guinea Pig Skin Sensitization - Challenge Readiness
Material: TOL-6BA Sample No.: 50-23A Conditions: N/A

Guinea Pig No.:	7-1427	7-1427	7-1427	7-1427	7-1427	7-1427	7-1427	7-1427	7-1427
Sex:	M								
Site/Time:	1	2	3	4	5	6	7		
Dosed by:									

Erythema & Eschar Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-14-87	0	0	0	0	0	0	0
1 day	7-15-87	8	1	0	0	0	0	0
2 days	7-16-87	8	0	0	0	0	0	0

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-14-87	0	0	0	0	0	0	0
1 day	7-15-87	0	0	0	0	0	0	0
2 days	7-16-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-14-87	0	0	0	0	0	0	0
1 day	7-15-87	0	0	0	0	0	0	0
2 days	7-16-87	0	0	0	0	0	0	0

Specific Effects/Remarks:

Initials: S-1621 Date: 7-14-87
H.R.T.-C.m - 3/29/88

KEY TO ABBREVIATIONS:

Severe Score

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score

d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

WPC/11f/11752-2
06-30-87

Guinea Pig Skin Sensitization Testing Dosage

Group: TOI Date: 7-13-87
Material/Sample No: 1. TOI - 6PSA / 50-331 2. TOL / 50-564
Vehicle/Sample No: 1. SALINE 2. ACETONE

Challenge Test Material	Animal Number / Sex	Site	Cone.	Dose (ml)	Route of Administra- tion	Time	Initials
GFS4	87-14688 Female	1	0.1%	0.1	INJECTION	11:37	✓✓
T02-GFS4		2	0.01%	0.1	INJECTION	11:38	✓✓
T02-GFS4		3	0.1%	0.1	INJECTION	11:39	✓✓
SALINE		4	0.9%	0.1	INJECTION	11:40	✓✓
T02		5	0.1%	0.1	TOPICAL	11:41	✓✓
T02		6	0.1%	0.1	TOPICAL	11:42	✓✓
ACETONE		7	100%	0.1	TOPICAL	11:43	✓✓
GFS4	87-14693 Female	1	0.1%	0.1	INJECTION	11:50	✓✓
T02-GFS4		2	0.01%	0.1	INJECTION	11:50	✓✓
T02-GFS4		3	0.1%	0.1	INJECTION	11:51	✓✓
SALINE		4	0.9%	0.1	INJECTION	11:51	✓✓
T02		5	0.1%	0.1	TOPICAL	11:52	✓✓
T02		6	0.1%	0.1	TOPICAL	11:52	✓✓
ACETONE		7	100%	0.1	TOPICAL	11:52	✓✓
GFS4	87-14697 Female	1	0.1%	0.1	INJECTION	11:53	✓✓
T02-GFS4		2	0.01%	0.1	INJECTION	11:53	✓✓
T02-GFS4		3	0.1%	0.1	INJECTION	11:54	✓✓
SALINE		4	0.9%	0.1	INJECTION	11:54	✓✓
T02		5	0.1%	0.1	TOPICAL	11:55	✓✓
T02		6	0.1%	0.1	TOPICAL	11:55	✓✓
ACETONE		7	100%	0.1	TOPICAL	11:55	✓✓
GFS4	87-14699 Female	1	0.1%	0.1	INJECTION	11:56	✓✓
T02-GFS4		2	0.01%	0.1	INJECTION	11:57	✓✓
T02-GFS4		3	0.1%	0.1	INJECTION	11:57	✓✓
SALINE		4	0.9%	0.1	INJECTION	11:58	✓✓
T02		5	0.1%	0.1	TOPICAL	11:59	✓✓
T02		6	0.1%	0.1	TOPICAL	11:59	✓✓
ACETONE		7	100%	0.1	TOPICAL	11:59	✓✓
					COMMENTS:		

HDB-F/118/11942
07/02/87

Guinea Pig Skin Sensitization Testing Dosage

Group: TOE Date: 7-13-87
Material/Sample No: 1. TOE - GFA / 50-311 2. TOE / 50-584
Vehicle/Sample No: 1. SALINE 2. ACETOIC

Challenge Test Material	Animal Number / Sex	Site	Cone.	Dose (ml)	Route of Administration	Time	Initials
6P:4 702-6P:4 702-6P:4 SALINE 70I 70I	87-14702 Female	1	0.1% 0.5%	0.1	TOPICAL	11:21	✓
		2	0.5%	0.1	TOPICAL	11:21	✓
		3	0.1%	0.1	TOPICAL	11:21	✓
		4	0.9%	0.1	TOPICAL	11:22	✓
		5	0.51%	0.1	TOPICAL	11:23	✓
		6	0.1%	0.1	TOPICAL	11:23	✓
ACETONE		COMMENTS:	?	100%	0.1	TOPICAL	11:34
6P:4 702-6P:4 702-6P:4 SALINE 70I 70I	87-14703 Female	1	0.1%	0.1	TOPICAL	11:34	✓
		2	0.5%	0.1	TOPICAL	11:35	✓
		3	0.1%	0.1	TOPICAL	11:35	✓
		4	0.9%	0.1	TOPICAL	11:35	✓
		5	0.51%	0.1	TOPICAL	11:36	✓
		6	0.1%	0.1	TOPICAL	11:37	✓
ACETONE		COMMENTS:	?	100%	0.1	TOPICAL	11:37
6P:4 702-6P:4 702-6P:4 SALINE 70I 70I	87-14706 Female	1	0.1%	0.1	TOPICAL	11:38	✓
		2	0.5%	0.1	TOPICAL	11:39	✓
		3	0.1%	0.1	TOPICAL	11:39	✓
		4	0.9%	0.1	TOPICAL	11:39	✓
		5	0.51%	0.1	TOPICAL	11:40	✓
		6	0.1%	0.1	TOPICAL	11:41	✓
ACETONE		COMMENTS:	?	100%	0.1	TOPICAL	11:41
6P:4 702-6P:4 702-6P:4 SALINE 70I 70I	87-14707 Female	1	0.1%	0.1	TOPICAL	11:35	✓
		2	0.5%	0.1	TOPICAL	11:35	✓
		3	0.1%	0.1	TOPICAL	11:36	✓
		4	0.9%	0.1	TOPICAL	11:37	✓
		5	0.51%	0.1	TOPICAL	11:38	✓
		6	0.1%	0.1	TOPICAL	11:39	✓
ACETONE		COMMENTS:	?	100%	0.1	TOPICAL	11:39
		COMMENTS:					
		COMMENTS:					
		COMMENTS:					
		COMMENTS:					
		COMMENTS:					

HDB-F/11f/1194Z
07/02/87

Guinea Pig Skin Sensitization Testing Dosage

Group: 701 Date: 9-13-87
Material/Sample No: 1. 702-6PSA / 50-512 2. 701 / 50-517
Vehicle/Sample No: 1. SALINAE 2. ACETONE

Challenge Test Material	Animal Number / Sex	Site	Conc.	Dose (ml)	Route of Administration	Time	Initials
GPSA TOE-6PSA TOE-6PSA SALINE TOE TOE ACETONE	87-14717 Female	1 2 3 4 5 6	0.1% 0.1% 0.1% 0.1% 0.1% 0.1%	0.1 0.1 0.1 0.1 0.1 0.1	INJECTION INJECTION INJECTION INJECTION TOPICAL TOPICAL	11:40 11:41 11:41 11:41 11:42 11:42	MM
	COMMENTS:	7	100%	0.1	TOPICAL	11:43	MM
GPSA TOE-6PSA TOE-6PSA SALINE TOE TOE ACETONE	87-14720 Female	1 2 3 4 5 6	0.1% 0.1% 0.1% 0.1% 0.1% 0.1%	0.1 0.1 0.1 0.1 0.1 0.1	INJECTION INJECTION INJECTION INJECTION TOPICAL TOPICAL	11:44 11:45 11:45 11:45 11:46 11:46	MM
	COMMENTS:	7	100%	0.1	TOPICAL	11:46	MM
GPSA TOE-6PSA TOE-6PSA SALINE TOE TOE ACETONE	87-14723 Female	1 2 3 4 5 6	0.1% 0.1% 0.1% 0.1% 0.1% 0.1%	0.1 0.1 0.1 0.1 0.1 0.1	INJECTION INJECTION INJECTION INJECTION TOPICAL TOPICAL	11:48 11:49 11:49 11:50 11:51 11:51	MM
	COMMENTS: route 7 = 0.1% TOE route 8 = 100% acetone	7	100%	0.1	TOPICAL	11:52	MM
GPSA TOE-6PSA TOE-6PSA SALINE TOE TOE ACETONE	87-14724 Female	1 2 3 4 5 6	0.1% 0.1% 0.1% 0.1% 0.1% 0.1%	0.1 0.1 0.1 0.1 0.1 0.1	INJECTION INJECTION INJECTION INJECTION TOPICAL TOPICAL	11:53 11:53 11:53 11:53 11:57 11:58	MM
	COMMENTS:	7	100%	0.1	TOPICAL	11:59	MM
	COMMENTS:						

MDB-F/11f/1194Z
07/02/87

Guinea Pig # 87-14688

<u>5</u> 0.01% TOZ	<u>6</u> 0.1% TOZ	<u>7</u> 100% Acetate
--------------------------	-------------------------	-----------------------------

0.1% GPA	0.01% TOZ-GPA	0.1% TOZ-GPA	Tail 0.9% SILVER
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14692

<u>5</u> 0.01% TOZ	<u>6</u> 0.1% TOZ	<u>7</u> 100% Acetate
--------------------------	-------------------------	-----------------------------

Head 0.1% GPA	0.01% TOZ-GPA	0.1% TOZ-GPA	Tail 0.8% Hogz SILVER
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14697

<u>5</u> 0.01% TOZ	<u>6</u> 0.1% TOZ	<u>7</u> 100% Acetate
--------------------------	-------------------------	-----------------------------

0.1% GPA	0.01% TOZ-GPA	0.1% TOZ-GPA	Tail 0.9% SILVER
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14699

<u>5</u> 0.01% TOZ	<u>6</u> 0.1% TOZ	<u>7</u> 100% Acetate
--------------------------	-------------------------	-----------------------------

Head 0.1% GPA	0.01% TOZ-GPA	0.1% TOZ-GPA	Tail 0.9% SILVER
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14702

<u>5</u> 0.9% TOZ	<u>6</u> 0.1% TOZ	<u>7</u> 100% Acetate
-------------------------	-------------------------	-----------------------------

Head 0.1% GPA	0.01% TOZ-GPA	0.1% TOZ-GPA	Tail 0.9% SILVER
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14703

<u>5</u> 0.01% TOZ	<u>6</u> 0.1% TOZ	<u>7</u> 100% Acetate
--------------------------	-------------------------	-----------------------------

Head 0.1% GPA	0.01% TOZ-GPA	0.1% TOZ-GPA	Tail 0.9% SILVER
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14706

<u>5</u> 0.0190 TOZ	<u>6</u> 0.0190 TOZ	<u>7</u> 100%
---------------------------	---------------------------	------------------

0.190 GPA	0.0190 TOZ-GPA	0.190 TOZ-GPA	Tail 0.99% spine
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

TPZ

Guinea Pig # 87-14707

<u>5</u> 0.0190 TOZ	<u>6</u> 0.0190 TOZ	<u>7</u> 100%
---------------------------	---------------------------	------------------

Head 0.190 GPA	Head 0.0190 TOZ-GPA	Head 0.190 TOZ-GPA	Tail 0.99% spine
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14717

<u>5</u> 0.0190 TOZ	<u>6</u> 0.0190 TOZ	<u>7</u> 100%
---------------------------	---------------------------	------------------

Head 0.190 GPA	Head 0.0190 TOZ-GPA	Head 0.190 TOZ-GPA	Tail 0.99% spine
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14720

<u>5</u> 0.0190 TOZ	<u>6</u> 0.0190 TOZ	<u>7</u> 100%
---------------------------	---------------------------	------------------

Head 0.190 GPA	Head 0.0190 TOZ-GPA	Head 0.190 TOZ-GPA	Tail 0.99% spine
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14723

<u>5</u> 0.0190 TOZ	<u>6</u> 0.0190 TOZ	<u>7</u> 100%
---------------------------	---------------------------	------------------

Head 0.190 GPA	Head 0.0190 TOZ-GPA	Head 0.190 TOZ-GPA	Tail 0.99% spine
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig # 87-14724

<u>5</u> 0.0190 TOZ	<u>6</u> 0.0190 TOZ	<u>7</u> 100%
---------------------------	---------------------------	------------------

Head 0.190 GPA	Head 0.0190 TOZ-GPA	Head 0.190 TOZ-GPA	Tail 0.99% spine
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>

Guinea Pig Skin Sensitization - Challenge Readings
TOX 50-56A
Material: TOX-6P34 Sample No.: 50-331 Conditions: NA

Date:	7-13-87	7-14-87	7-15-87				
Guinea Pig No.:	67-1483						
Sex:	♀						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	mm						

Erythema & Eschar Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	~ 7-13-87	0	IP	IP	IP	0	C	0
1 day	~ 7-14-87	0	IP	1	IP	0	0	0
2 days	~ 7-15-87	0	0	0	0	0	0	0

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	~ 7-13-87	0	0	0	0	0	0	0
1 day	~ 7-14-87	0	0	0	0	0	0	0
2 days	~ 7-15-87	0	0	C	C	C	0	0

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	~ 7-13-87	0	0	0	0	0	0	0
1 day	~ 7-14-87	0	0	0	0	0	0	0
2 days	~ 7-15-87	0	0	C	C	C	0	0

Specific Effects/Remarks:

① - ~~Ingot~~ ~~small~~ ~~reaction~~
~~reaction~~
small reaction ~

Initials: J.W.R. Date: 7-13-87

KEY TO ABBREVIATIONS:

Severe Score

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
SC=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score

d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

Guinea Pig Skin Sensitization - Challenge Readiness

Material: T02-6054 Date: 80-564
 Sample No.: 50-32A Conditions: MV

Guinea Pig No.:	1-1487	7-4-87	7-15-87				
Sex:	<u>♂</u>						
Site/Time:	1	2	3	4	5	6	
Dosed by:	<u>ME</u>						

Erythema & Eczema Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	HR Ave. Score
4-6 hours	7-5-87	0	IP	IP	IP	IP	0	0
1 day	7-17-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Edema Formation

Time:	Date/ Init.	Score	Score	Score	Score	Score	Score	HR Ave. Score
4-6 hours	7-5-87	0	0	0	0	0	0	0
1 day	7-17-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/ Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

(1) - Tinge de Peau
for all aged sites

Initials JL Date 7-13-87

KEY TO ABBREVIATIONS:

Severe Score
 D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
 S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score
 d=desquamation; n=necrosis; ec=ecchymosis;
 s=scab formation f=fissuring; u=ulceration

Guinea Pig Skin Sensitization - Challenge Readiness

Material: 703-6PA Sample No.: 5-3A Conditions:

Date:	7-13-67	7-14-67	7-15-67				
Guinea Pig No.:	51-97						
Sex:	M						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	sm						

Erythema & Xanthar Formation

Time (After Initiation of Contact):	Date/ Init.	Score	Avg. Score						
4-6 hours	7-5-71	1P	1P	1P	1P	0	0	0	
1 day	7-17-71	0	1P	1	1P	0	0	0	
2 days	7-18-71	0	0	1	1	0	0	0	

Edema Formation

Time:	Date/ Init.	Score	Score	Score	Score	Score	Score	Avg. Score
4-6 HOURS	7-17-77	8	8	0	0	0	0	0
1 day	7-17-77	8	8	0	0	0	0	0
2 days	7-18-77	8	8	0	0	0	0	0

Other Illustration of Effects

Specific Effects/Remarks:

⑧ - Target-Position
for all right site

Original ٦٢٨ Page ٧-٣-٩

KEY TO ABBREVIATIONS

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
SC=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Scars
d=desquamation; n=necrosis; ec=ecchymosis;
s=sab formation f=fissuring; u=ulceration

WPC/11f/11732-2
06-10-87

Guinea Pig Skin Sensitization - Challenge Readiness

TOI Sample No.: 50-334 Conditions: MA

Material: TOI-654

Date:	7-13-87	7-14-87	7-15-87				
Guinea Pig No.:	17-14699						
Sex:	♀						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	<u>MA</u>						

Erythema & Eczema Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-13-87	0	1P	1P	1P	0	0	0
1 day	7-14-87	0	2S	1	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-13-87	0	0	0	0	0	0	0
1 day	7-14-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:
*dry skin function
for all agents etc*

Initials D Date 7-13-87

KEY TO ABBREVIATIONS:

Severe Score
D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score
d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

WPC/11f/1175Z-2
06-30-87

702 Guinea Pig Skin Sensitization - Challenge Readings
Material: T02-684 Sample No.: SD-332 Conditions: NK

Date:	7-13-87	7-14-87	7-15-87				
Guinea Pig No.:	57-14702						
Sex:	M						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	X						

Erythema & Eoschar Formation

Time (After Initiation of Contact):	Date/Init.							Ave. Score
4-6 hours	7-13-87	0	1	1	1	0	0	0.5
1 day	7-14-87	0	0	1	2	0	0	0.5
2 days	7-15-87	0	0	0	0	0	0	0

Edema formation

Time:	Date/Init.							Ave. Score
4-6 hours	7-13-87	0	0	0	0	0	0	0
1 day	7-14-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/Init.							Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

0 - Ingotie Punkte
fr alligatörische

Initials Dan W D Date 7-13-87

KEY TO ABBREVIATIONS:

Severe Score	Minor Score
D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;	d=desquamation; n=necrosis; ec=ecchymosis;
S=SCAB FORMATION F=FISSURING; U=ULCERATION	s=scab formation f=fissuring; u=ulceration

WPC/11f/11752-2
06-30-87

TOD Guinea Pig Skin Sensitization - Challenge Readings
Material: 702-6954 Sample No.: 5-3 Conditions: NA

Date:	7-13-87	7-14-87	7-15-87				
Guinea Pig No.:	57-1763						
Sex:	M						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	X						

Erythema & Eschar Formation

Time (After Initiation of Contact):	Date/Init.							7-13-87
4-6 hours	7-13-87	0	10	10	10	10	0	0
1 day	7-14-87	10	10	10	10	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Edema Formation

Time:	Date/Init.							7-13-87
4-6 hours	7-13-87	0	0	0	0	0	0	0
1 day	7-14-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/Init.							Ave. Score
4-6 hours	7-13-87	0	0	0	0	0	0	0
1 day	7-14-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Specific Effects/Remarks:

(+) - Transient Pustules
found on right side

Initials D W. Tad Date 7-13-87

KEY TO ABBREVIATIONS:

Severe Score

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score

d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

WPC/11f/11752-2
06-30-87

TOI Guinea Pig Skin Sensitization - Challenge Readings							
Material:	TOI-GPA	Sample No.:	50-33A	Conditions:	NA		
Date:	7-13-87	7-14-87	7-15-87				
Guinea Pig No.:	174706						
Sex:	M						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	LP						

Erythema & Eczema Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-13-87	0	0	0	0	0	0	0
1 day	7-14-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-13-87	C	0	0	0	0	G	C
1 day	7-14-87	0	0	0	0	0	0	0
2 days	7-15-87	C	C	0	0	0	0	C

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

O - Ingrat Pus
for elongated site

Initials DWJ Date 7-13-87

KEY TO ABBREVIATIONS:

Severe Score

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
SC=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score

d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

T0I Guinea Pig Skin Sensitization - Challenge Readiness

Material: T0I-GSA Sample No.: 50-G4 Conditions: AA

Date:	7-1-87	7-1-87	7-1-87				
Guinea Pig No.:	12-207						
Sex:	M						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	WY						

Erythema & Eczematous Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-3-87	0	1	6	1	1	0	3
1 day	7-4-87	0	0	0	0	0	0	0
2 days	7-5-87	0	0	0	0	0	0	0

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-3-87	0	0	0	0	0	0	0
1 day	7-4-87	0	0	0	8	0	0	0
2 days	7-5-87	0	2	0	0	0	0	0

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

O=Injury-Painful
for all intact sites

Initials: D J.W. Red Date: 7-13-87

KEY TO ABBREVIATIONS:

Severe Score

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score

d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

Guinea Pig Skin Sensitization - Challenge Readings

Material: T01-6PSA Date: 7-13-87 Sample No.: SP-122 Conditions: NA

Date:	7-13-87	7-14-87	7-15-87				
Guinea Pig No.:	<u>12-1717</u>						
Sex:	<u>F</u>						
Site/Time:	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>
Dosed by:	<u>DC</u>						<u>HG 7-13-87</u>

Erythema & Eschar Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	<u>7-13-87</u>	<u>0</u>	<u>IP</u>	<u>IP</u>	<u>IP</u>	<u>IP</u>	<u>0</u>	<u>0</u>
1 day	<u>7-14-87</u>	<u>0</u>	<u>0</u>	<u>1</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
2 days	<u>7-15-87</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	<u>7-13-87</u>	<u>0</u>						
1 day	<u>7-14-87</u>	<u>0</u>						
2 days	<u>7-15-87</u>	<u>C</u>	<u>C</u>	<u>C</u>	<u>C</u>	<u>C</u>	<u>C</u>	<u>0</u>

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

O-Injek-Punkte
fallow injek site

Initials: 1420 Date: 7-13-87

KEY TO ABBREVIATIONS:

Severe Score

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
 S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score

d=desquamation; n=necrosis; ec=ecchymosis;
 s=scab formation f=fissuring; u=ulceration

701 Guinea Pig Skin Sensitization - Challenge Readiness
Material: 702-GPSA Sample No.: 50-33A Conditions: NA

Date:	1-1-87	1-4-87	1-7-87				
Guinea Pig No.:	47-4720						
Sex:	♀						
Site/Time:	1	2	3	4	5	6	?
Dosed by:							

Erythema & Pachar Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	1-1-87	0	1	0	1	0	0	0.33
1 day	1-4-87	0	1	0	0	0	0	0
2 days	1-7-87	0	1	1	0	0	0	0.33

Edema Formation

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	1-1-87	0	0	0	0	0	0	0
1 day	1-4-87	0	0	0	0	0	0	0
2 days	1-7-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

U=Infiltration
at all injection sites

Initials D W Date 1-7-87

KEY TO ABBREVIATIONS:

Severe Scores
D=DESKAMATION; N=NECROSIS; EC=ECCHYMOSIS;
S=SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Scores
d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

WPC/11f/1175Z-2
06-30-87

702 Guinea Pig Skin Sensitization - Challenge Readings
 Material: 702-689 Sample No.: 50-332 Conditions: *NA*

Date:	7-13-87	7-14-87	7-15-87					
Guinea Pig No.:	702-689							
Sex:	♀							
Site/Time:	1	2	3	4	5	6	7	8
Dosed by:	<i>me</i>							

Erythema & Eschar Formation

Time (After Initiation of Contact):	Date/Init.	Score	Score	Score	Score	Score	Score	Avg. Score
4-6 hours	7-13-87	0	1+	1+	2+	2+	0	0.2
1 day	7-14-87	1+	1+	1+	2+	0	0	0.2
2 days	7-15-87	0	1	1	1+	0	0	0.2

Edema Formation

Time:	Date/ Init.	Score	Score	Score	Score	Score	Score	Avg. Score
4-6 hours	7-13-87	0	0	0	0	0	0	0
1 day	7-14-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/ Init.	Score	Score	Score	Score	Score	Score	Avg. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

*0 - Irrelevant
for all sites*

Initials *DL* Date *7-13-87*

KEY TO ABBREVIATIONS:

Severe Score
 D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
 ESCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score
 d=desquamation; n=necrosis; ec=ecchymosis;
 e=escab formation f=fissuring; u=ulceration

WPC/118/11752-2
06-30-87

TOI Guinea Pig Skin Sensitization - Challenge Readings
Materials: T02-6P5A Sample No.: 5-332 Conditions: MA

Date:	7-13-87	7-14-87	7-15-87				
Guinea Pig No.:	1714744						
Sex:	♀						
Site/Time:	1	2	3	4	5	6	7
Dosed by:	IV						

Erythema & Eschar Formation

Time (After Initiation of Contact)	Date/Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-13-87	0	1	1P	1P	1P	0	0
1 day	7-14-87	0	0	1	1P	0	0	0
2 days	7-15-87	0	0	1	1P	0	0	0

Edema Formation

Time:	Date/ Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours	7-13-87	0	0	0	0	0	0	0
1 day	7-14-87	0	0	0	0	0	0	0
2 days	7-15-87	0	0	0	0	0	0	0

Other Irritation or Effects

Time:	Date/ Init.	Score	Score	Score	Score	Score	Score	Ave. Score
4-6 hours								
1 day								
2 days								

Specific Effects/Remarks:

B-2 injections
for all sites
7-13-87

Initials D W D Date 7-13-87

KEY TO ABBREVIATIONS:

Severe Score

D=DESQUAMATION; N=NECROSIS; EC=ECCHYMOSIS;
SCAB FORMATION F=FISSURING; U=ULCERATION

Minor Score

d=desquamation; n=necrosis; ec=ecchymosis;
s=scab formation f=fissuring; u=ulceration

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